

Notice of Allowability

Application No.

10/041,018

Examiner

Delia M. Ramirez

Applicant(s)

MATSUDA ET AL.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 12/13/2005.
2. ☒ The allowed claim(s) is/are 1,4-18,29,32,80-115,117-120,122-129,132-134 and 142-151.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

DETAILED ACTION

Status of the Application

Claims 1, 4-18, 29, 32, 80-115, 117-120, 122-129, 132-134 are pending.

Amendment of claims 10, 80, 87, 92, 102-111, 113-115, 117-120, 122-129, 132-134, and cancellation of claims 116, 121, 130-131, 135-141 in a communication filed on 12/13/2005 is acknowledged.

In a telephone conversation with Michelle LeCointe on 3/10/2006, an agreement was reached to amend claims 80, 92, 102-111, 114-115, 119-120, and add claims 142-151 to place the application in condition for allowance.

Examiner's Amendment

1. An Examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

2. Authorization for this Examiner's amendment was given in a telephone interview with Michelle LeCointe on 3/8/2006.

3. Please replace claims 80, 92, 100-111, 114-115, 119-120 as follows:

80. The unicellular organism of claim 10, wherein said unicellular organism further comprises a fourth exogenous nucleic acid encoding a sterol uptake control transcription factor under control of a fourth promoter operable in said organism.

92. The unicellular organism of claim 87, wherein said unicellular organism further comprises a fourth exogenous polynucleotide encoding a sterol uptake control transcription factor under control of a fourth promoter operable in said organism.

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100. The unicellular organism of claim 91, wherein said fourth polynucleotide and promoter are operable to confer to said organism an increase in sterol metabolic flux as compared to native sterol metabolic flux levels.

101. The unicellular organism of claim 92, wherein said fourth polynucleotide and promoter are operable to confer to said organism an increase in sterol metabolic flux as compared to native sterol metabolic flux levels.

102. The unicellular organism of claim 1, wherein said first exogenous nucleic acid and first promoter are contained in a vector.

103. The unicellular organism of claim 1, wherein said second exogenous nucleic acid and second promoter are contained in a vector.

104. The unicellular organism of claim 10, wherein said third exogenous nucleic acid and third promoter are contained in a vector.

105. The unicellular organism of claim 14, wherein said fourth exogenous nucleic acid and fourth promoter are contained in a vector.

106. The unicellular organism of claim 80, wherein said fourth exogenous nucleic acid and fourth promoter are contained in a vector.

107. The unicellular organism of claim 29, wherein said first exogenous polynucleotide and first promoter are contained in a vector.

108. The unicellular organism of claim 29, wherein said second exogenous polynucleotide and second promoter are contained in a vector.

109. The unicellular organism of claim 87, wherein said third exogenous polynucleotide and third promoter are contained in a vector.

110. The unicellular organism of claim 91, wherein said fourth exogenous polynucleotide and fourth promoter are contained in a vector.

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111. The unicellular organism of claim 92, wherein said fourth exogenous polynucleotide and fourth promoter are contained in a vector.

114. The unicellular organism of claim 10, further comprising a first enhancer operable to enhance transcriptional activation of the first nucleic acid.

115. The unicellular organism of claim 114, further comprising a second enhancer operable to enhance transcriptional activation of the second nucleic acid.

119. The unicellular organism of claim 87, further comprising a first enhancer operable to enhance transcriptional activation of the first polynucleotide.

120. The unicellular organism of claim 119, further comprising a second enhancer operable to enhance transcriptional activation of the second polynucleotide.

4. Please add the following claims:

142. The unicellular organism of claim 115, further comprising a third enhancer operable to enhance transcriptional activation of the third nucleic acid.

143. The unicellular organism of claim 14, further comprising a first enhancer operable to enhance transcriptional activation of the first nucleic acid.

144. The unicellular organism of claim 143, further comprising a second enhancer operable to enhance transcriptional activation of the second nucleic acid.

145. The unicellular organism of claim 144, further comprising a third enhancer operable to enhance transcriptional activation of the third nucleic acid.

146. The unicellular organism of claim 145, further comprising a fourth enhancer operable to enhance transcriptional activation of the fourth nucleic acid.

147. The unicellular organism of claim 120, further comprising a third enhancer operable to enhance transcriptional activation of the third polynucleotide.

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148. The unicellular organism of claim 91, further comprising a first enhancer operable to enhance transcriptional activation of the first polynucleotide.

149. The unicellular organism of claim 148, further comprising a second enhancer operable to enhance transcriptional activation of the second polynucleotide.

150. The unicellular organism of claim 149, further comprising a third enhancer operable to enhance transcriptional activation of the third polynucleotide.

151. The unicellular organism of claim 150, further comprising a fourth enhancer operable to enhance transcriptional activation of the fourth polynucleotide.

Reasons for Allowance

5. The following is an Examiner's statement of reasons for allowance. Although the prior art discloses the nucleic acids of SEQ ID NO: 1, 361, 399, and nucleic acids encoding the polypeptides of SEQ ID NO: 22, 383, the Examiner has found no teaching or suggestion in the prior art directed to a unicellular organism comprising a first exogenous nucleic acid comprising SEQ ID NO: 1, and a second exogenous nucleic acid comprising SEQ ID NO: 361. The nucleic acid of SEQ ID NO: 1 encodes the protein of SEQ ID NO: 22, which is the *S. cerevisiae* BTS1 gene product (geranylgeranyl pyrophosphate synthase), the nucleic acid of SEQ ID NO: 361 encodes the protein of SEQ ID NO: 383, which is the *Stevia rebaudiana* diterpene synthase, and the nucleic acid of SEQ ID NO: 399 encodes the product of the *S. cerevisiae* upc2-1 allele. A unicellular organism comprising all three nucleic acids (i.e., SEQ ID NO: 1, 361 and 399) would not be obvious to one of skill in the art since there is no motivation to combine those specific nucleic acids in a unicellular organism as claimed. Therefore, claims 1, 4-18, 29, 32, 80-115, 117-120, 122-129, 132-134 and 142-151 directed to a unicellular organism comprising (1) an exogenous nucleic acid comprising SEQ ID NO: 1 and an exogenous nucleic acid comprising SEQ ID NO: 361, or (2) an exogenous nucleic acid comprising SEQ ID NO: 1, an exogenous nucleic acid

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comprising SEQ ID NO: 361, and an exogenous nucleic acid comprising SEQ ID NO: 399, (3) an exogenous nucleic acid encoding the polypeptide of SEQ ID NO: 22 and an exogenous nucleic acid encoding the polypeptide of SEQ ID NO: 383, or (4) an exogenous nucleic acid encoding the polypeptide of SEQ ID NO: 22, an exogenous nucleic acid encoding the polypeptide of SEQ ID NO: 383, and an exogenous nucleic acid comprising SEQ ID NO: 399, are allowable over the prior art of record.

Conclusion

6. Claims 1, 4-18, 29, 32, 80-115, 117-120, 122-129, 132-134 and 142-151 are allowed.
7. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."
8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Delia M. Ramirez, Ph.D.
Patent Examiner
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DR
March 13, 2006


REBECCA E. PROUTY
PRIMARY EXAMINER
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1600